

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 4 CASES ON ATTACHED EXHIBIT A	

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF TED ROTH, M.D.**

Plaintiffs state as follows in support of their motion seeking to preclude defense expert Ted Roth, M.D., a urogynecologist, from giving opinions on: (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"); (2) the design of Defendants' transvaginal mesh products at issue, including whether or not the design of those devices is reasonable; (3) any opinions regarding the safety and efficacy of TVT or TVT-O, or in the alternative, any opinions regarding differences in safety and efficacy rates between the TVT mechanically cut mesh and the TVT laser cut mesh; and (4) his statements about the safety and efficacy of Defendants' products based on his own practice.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and

methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony “must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, “the factors discussed in *Daubert* were neither definitive, nor exhaustive.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because “*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Roth from giving the opinions referenced above because he is not qualified to opine on those issues, applies a flawed methodology and standard for arriving at his opinions and has not done the necessary research to produce opinions that can reliably be applied to this case.

Dr. Roth has issued two reports in this litigation, one addressing the TVT and TVT-O, (General TVT & TVT-O Expert report of Ted Roth, M.D., Exhibit B); and one addressing the Prolift +M, Prolift, and Gynemesh PS (General Prolift, Prolift +M, and Gynemesh PS Expert report of Ted Roth, M.D., Exhibit C), hereinafter “subject products.”¹ These reports contain the following general opinions:

- The risks conveyed in the Prolift and Gynemesh PS IFUs, and in Ethicon’s professional education materials, are appropriate because they accurately reflect the risks reported in peer reviewed medical literature, those observed by experienced pelvic surgeons such as myself and those discussed by my peers at medical conferences. (Ex. C at 27).
- Both Prolift and Prolift+M have been demonstrated to be safe and effective. (*Id.* at 28).
- The IFU for the TVT line of products, as well as Ethicon’s professional education materials, appropriately warn of the risks of the devices. (Ex. D at 27).

¹ Although Dr. Roth’s Prolift +M report also encompasses the Prolift and Gynemesh PS devices, Dr. Roth is not being offered as an expert on the Prolift or Gynemesh PS device at this time. See (Roth Deposition, 3-17-2017, 37:4-19; Exhibit. D)

- Experienced surgeons are aware of the intraoperative and post-operative risks inherent in the use of surgical mesh. (*Id.* at 28)
- “Mid-urethral sling operations have been the most extensively researched surgical treatment for SUI in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term.” (*Id.* at 5)

The first and third bullet points contain opinions expressly directed to the adequacy of the warnings and IFU accompanying the subject products. Further, the opinion regarding what experienced surgeons know about the risks inherent with the use of surgical mesh is speculation.

The second and final bullet point does not use the word “design,” but it clearly is an opinion about the subject products’ design. The opinion uses phrases such as “safe and effective” and “good safety profile,” and thus it addresses the risk-utility test, which is part of the inquiry into a design defect claim in many states. Further, Dr. Roth impermissibly lumps together all mid-urethral slings into a single category in his analysis of whether the TVT and TVT-O devices are safe and effective. Dr. Roth should not be permitted to offer these legal conclusions and design opinions based on flawed methodology.

For the reasons below, Dr. Roth should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. DR. ROTH’S OPINION ON THE ADEQUACY OF DEFENDANTS’ WARNINGS SHOULD BE EXCLUDED PURSUANT TO DAUBERT

Dr. Roth’s opinions on the adequacy of Defendants’ warnings are based on precisely the *ipse dixit* that the Supreme Court has found inadmissible. Dr. Roth admits he is wholly unaware of the applicable FDA standards governing what risk information medical devices companies are required to put in IFUs. He testifies that he does not believe the IFU need to include all significant risks associated with the use of the device, despite reviewing and relying on the Blue

Book standard which states a contrary standard. He is testifying solely based on his status as a surgeon and thus his knowledge of what a surgeon needs to know. While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer testimony about what information should be included in an IFU. *See Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Roth does not possess the additional expertise to offer expert testimony about what the IFU should include.

Federal courts agree that *ipse dixit* opinions—which are justified solely by the fact that the expert holds them—are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) (“If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.”).

This Court has also excluded *ipse dixit* opinions in this transvaginal mesh litigation, and other product liability litigations. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013) (excluding testimony where expert’s “opinions are simply *ipse dixit* opinions”) *see also, e.g., In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 840 (S.D. W. Va. 2011) (Goodwin, J.) (“Dr. Mason's reason for using the long-delayed draw in his analysis is this: ‘[I]t's what I've got. And that's the way I'm doing it.’ That is *ipse dixit* condemned by *Daubert* and its progeny.”). *See also Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680814, at *6 (S.D. W. Va. July 8, 2011) (excluding expert testimony because of the analytical gap between the data and opinions derived).

Dr. Roth has admitted that his opinions regarding the adequacy of Defendants’ warnings are not based on any objective standards. He has no criteria of any kind:

Q. Do you know what FDA standards govern what risk information medical device companies are required to put in their IFUs]?

A. I don't.

Q. Do you know what industry standards govern what risk information companies are required to put in the IFUs?

A. I don't

Q. Do you know what departments medical device – of a medical device company are involved in creating the warnings and precautions section or the adverse reaction section of any IFU?

A. Not specifically, no

(Roth Deposition, 4-13-2017, 37:4-19; Exhibit E).

Dr. Roth not only is unaware of the standard with regard to the IFU, he also has no idea how to answer the question of whether an applicable IFU needs to include all the significant risks and complications:

Q. Would you agree that the warnings and adverse reactions section of the TVT IFU should include all the significant risks and complications related to the TVT or TVT-O?

A. **I don't know.** When you say --, when you say all, I think, you know, there are certain complications that are known to physicians doing these surgeries. I don't know that you need an exhaustive list of every one of them for people you are – are doing this.

(*Id.* at 130:10-21 (Emphasis added).

Dr. Roth has never read any testimony of Ethicon employees regarding Ethicon's position on what needs to be in an IFU with regard to risk information.² He has never been involved in drafting an IFU for a medical device or prescription drug.³ Although his expert report discusses the FDA blue book labeling standard and 21 CFR 801.109(c),⁴ it is clear from

² Ex. E at 128:17-21

³ *Id.* at 128:22-129:7

⁴ Ex. C at 31.

his testimony he does not know what standards apply to the IFU for a medical device, nor how to apply those standards. Further, it is unknown what materials Dr. Roth reviewed or did not review from his reliance list, as Dr. Roth's testimony makes clear that his reliance list does not contain an accurate list of the facts or data considered by him in forming his opinions as required by F.R Civ. P 26(a)(2)(B)(ii). Dr. Roth testified that his reliance list contains materials that he did not actually review.⁵ Further, he testified that he did not give final approval to his reliance list prior to it being served.⁶ This violates F.R Civ. P 26(a)(2)(B)(ii), and leaves Plaintiffs with an incomplete understanding of the facts and materials Dr. Roth utilized to support his opinions. Given that Dr. Roth's testimony indicates that he did not actually review or rely on any objective standard for his opinions that the pelvic mesh IFUs are adequate, the Court should prohibit this opinion under Fed. R. Civ. P 37(c)(1), and also under *Daubert*.

In addition to Dr. Roth's failure to disclose the materials he relied on in forming his opinions, Dr. Roth's opinion is the very *ipse dixit* testimony that *Daubert* was intended to prevent.⁷ In addition, Dr. Roth admits he engaged in no analysis to determine whether his opinion that certain risks are commonly known, and he cannot state what the knowledge base of other individuals or their experiences is or whether his knowledge is consistent with that of anyone else:

Q. My question was can you state to a reasonable degree of medical certainty the percentage of pelvic floor surgeons in the United States who knew or didn't know about that particular risk [excessive contraction or shrinkage of the mesh, vaginal scarring, tightening, or shortening that may occur] during the time the Prolift +M mesh was sold?

⁵ Ex. E, 43:17-46:9

⁶ Id. at 46:2-9

⁷ "*Ipse dixit*" is "a statement relying for truth upon the fact it has been said: and which is not independently justified or corroborated." JOHN GRAY, LAWYER'S LATIN: A *VADE-VECUM* 76 (2002).

- A. **I can't say what other people what their knowledge base was or what their experiences were.** These risks, these adverse reactions were commonly known.

(Ex. D at 59:10-21 (emphasis added)).

Dr. Roth admits he has no idea what is required to be an IFU or product warning by any standard. He did no research or analysis on that subject, or the subject of what percentage of surgeons actually knew about particular adverse reactions, but instead relies on his personal convictions on the subject.⁸ Dr. Roth has admitted that his opinions are not based on any objective standard. Those opinions are thus inadmissible under the *Daubert* line of cases.

II. DR. ROTH SHOULD BE PRECLUDED FROM GIVING DESIGN OPINIONS.

a. Dr. Roth has expressly testified that he is not a design expert or materials expert

As a primary issue, Dr. Roth should be precluded from opining about the design of the subject products, including offering opinions on the most suitable mesh for the treatment of SUI or POP. Dr. Roth admits he is not an expert on design of medical devices or mesh and has no opinions regarding the design:

Q. Do you consider yourself an expert on the design of medical devices?

A. Not in the sense where – I've not designed a medical device, but I'm familiar with sort of the history of the sling. But I'm not a biomedical engineer

Q. Are you going to offer any opinions in this case specifically regarding the design of the TVT or the TVT-O?

A. In regards to?

Q. Just the overall design

A. No.

(Ex. E. at 131:18-132:5).

⁸ Ex. D at 58:8-59:21

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Roth, who admitted during his deposition that he is not an expert on design or materials selection. As such, he should be precluded from giving any opinions related to design of the subject products.

b. Dr. Roth did not review Defendants' key documents related to product design, and even if he had reviewed them, Dr. Roth has no base of knowledge as to what those documents would demonstrate.

Dr. Roth should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the Boston Scientific litigation. Boston Scientific Corp. ("BSC") moved to exclude Dr. Bob Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

The same analysis applies to Dr. Roth in this case. He confirmed that he did not review Defendants' Design History File, design failure modes effects analysis, or any other internal design documents in formulating his opinions:

Q. Do you know what a design history file is?

A. I do not.

Q. Do you know what an application failure modes and effects analysis is?

A. No.

Q. Since you don't know what a design failure modes effects analysis is or an application modes failure analysis is, you would agree that you wouldn't offer an opinions regarding either of those analysis with regard to the TVT or TVT-O, correct?

[def. counsel] Object to form.

A. Correct

(Ex. E, 135:2-20).

Dr. Roth has admitted that he has not reviewed and is not familiar with any of Ethicon's internal design standard operating procedures related to the design of medical devices.⁹ He admitted he does now know what kind of experts Ethicon would need to use in designing a pelvic mesh medical device.¹⁰ He also does not know whether or not the IFU is part of the design failure modes effects analysis.¹¹ Because he did not review the relevant design documents, and has not done the appropriate analysis with regard to the design of the products Dr. Roth lacks the required knowledge and foundation to give a reliable opinion about the design and reasonableness of Defendants' transvaginal mesh products, including but not limited to

⁹ Ex. E 136:5-10

¹⁰ *Id.* at 133:17-134:7

¹¹ *Id.* at 135:22-136:4

whether or not the design of the devices was reasonable. Based on the foregoing, all Dr. Roth's opinions on the issue of product design should be excluded.

III. DR. ROTH SHOULD BE PRECLUDED FROM GIVING OPINIONS REGARDING THE SAFETY AND EFFICACY OF THE TVT AND TVT-O AS THEY ARE BASED ON AN UNRELIABLE ASSESSMENT OF ALL MID-URETHRAL SLINGS

The Court should preclude Dr. Roth from testifying that TVT or TVT-O devices are safe because, as set forth below, his opinions about TVT complications and complication rates are unreliable. Throughout his report, Dr. Roth repeatedly comments on the safety of the "mid urethral sling" rather than the TVT and TVT-O.¹² Dr. Roth admits that the TVT and TVT-O themselves are different products with different complication rates and have a different safety profile, yet he has chosen to combine his opinions into a single report.¹³ Nowhere in his report does he provide information regarding the differences in safety and efficacy between the TVT and TVT-O. More troubling, Dr. Roth relies heavily on meta-analyses of mid-urethral slings which include multiple other mid-urethral slings besides the TVT and TVT-O, including the Novara, Rheman, Barber, and Schimpf studies.¹⁴ For example, the Schimpf study included other slings besides the TVT and TVT-O, including the I-stop, the Monarc, the TVT Secur, and the Safyre device.¹⁵ However, Dr. Roth did not apply any reliable methodology to determine that the results of those studies were applicable to the TVT device:

Q. So in forming your – in relying on that material in forming your conclusion that specifically the TVT and not the midurethral sling as a better overall cure rate than the open burch, what methodology did you use to eliminate all those other slings in forming your conclusion regarding the TVT sling as opposed to midurethral slings in general?

[def. counsel] Objection

¹² Ex. B, at 5, 6, 9, 25.

¹³ Id. at 16:14-19, 17:21-18:10

¹⁴ Ex. B at 7-8

¹⁵ Ex. E at 167:15-23

- A. I don't think you can take—unfortunately you can't take out a meta-analysis and dissect out, you know the individual studies. I mean, you can look at the individual studies – and look at the sling versus the Burch, but I don't think you can take the end product, which is the meta-analysis, and then, you know, retroactively tease out how well the Burch did. You just have to look at those- or excuse me – or how well the J&J TVT did. You just have to look at those individual studies.

- Q. Right. So you'd agree for example, in the Schimpf study you took out all of the other manufacturers' slings and just compared TVT retropubic to open Burch or all the studies involving TVT retropubic to open Burch, you might reach a different conclusion, correct?

[def. counsel] Objection

- A. **I mean, that's possible.**¹⁶

This court should exclude Dr. Roth's opinions regarding the Safety and Efficacy of the TVT and TVT-O as unreliable and his opinions regarding all mid-urethral slings as a group as irrelevant, confusing and misleading to the jury, and otherwise improper. He cherry-picks data, cannot cite support for his opinions in the medical literature, and fails to explain how he distinguishes the safety and efficacy rates of the TVT and TVT-O from all mid-urethral slings. He fails to explain how he distinguished the safety and efficacy rates of the TVT from the TVT-O, despite conceding that they have different safety and efficacy rates. For those reasons, he should not be allowed to testify regarding the TVT and TVT-O's safety and efficacy rates.

IV. DR. ROTH'S OPINIONS ABOUT HIS PERSONAL EXPERIENCE RELATED TO THE SAFETY AND EFFICACY OF THE PELVIC MESH PRODUCTS SHOULD BE EXCLUDED BECAUSE THEY ARE NOT BASED ON ANY OBJECTIVE STANDARD, AND HIS ANALYSIS AND METHODOLOGY ARE FLAWED

Dr. Roth should be precluded from testifying about his perceived safety, efficacy, and patient satisfaction rates with the subject products from his practice, as those opinions are

¹⁶ Id at 167:24-168:22; 169:6-14 (emphasis added).

entirely unsupported by any reliable methodology, and have not been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016).

Dr. Roth has stated in his deposition that he intends to offer an opinion that his own patients who have been implanted with the Prolift +M device have between an 8 and 15 percent exposure rate.¹⁷ However, in arriving at this opinion, Dr. Roth admits he does not know how many patients that is based on, and he does not know the numbers of exposures between Prolift and Prolift +M kits. In addition, his opinion is not based on any kind of formal analysis where he determined the exact number of patients, the number of patients that were lost to follow-up, or any standardized evaluation protocol. He just “feels” his mesh exposure rate is anywhere from 8 to 15 percent¹⁸

Dr. Roth also stated that he intends to offer an opinion that the efficacy between the TVT mechanically cut and the laser cut is the same in his hands, and that the safety profile between the mechanically cut and laser cut mesh is the same based on a retrospective review of his own patients.¹⁹ However, Dr., Roth has admitted that this retrospective review is based on only 50 charts, he pulled them randomly from the laser cut group and the mechanically cut group, and just “sort of looked through their records.”²⁰ He cannot state definitely the average length of follow-up, he has not done any kind of written analysis, he does not know what percentage of patients were lost to follow up, and he admits, “it was not a very rigorous analysis.”²¹

¹⁷ Ex. D at 47:23-48:12

¹⁸ *Id.* at 48:13-50:10

¹⁹ Ex. E at 20:22-21:18; 23:11-15

²⁰ *Id.* at 24:25-12

²¹ *Id.* at 25:13-26:3

Moreover, in the event that this court does not grant Plaintiff's motion to exclude Dr. Roth from testifying about the safety and efficacy rates of the TVT and TVT-O devices, the court should, in the alternative, prohibit Dr. Roth from testifying about any difference in safety and efficacy rates between the TVT mechanically cut mesh and the TVT laser cut mesh, as Dr. Roth has admitted that his opinions in that regard are rooted solely on his flawed, unreliable analysis of his own patients, and "[g]lobally, I can't make a comment on that."²²

Dr. Roth's opinions about safety and efficacy rates among his own patients is inappropriate, unsupported, and inadmissible, and is exactly the kind of foundationless testimony this court has excluded in the past. He lacks any reliable methodology or analysis to support his conclusions. In addition, allowing Dr. Roth to offer an opinion as to his safety and efficacy rates for his own patients would be confusing and misleading to a jury, and therefore should be excluded under Rule 403. Because there is no foundation for his opinions, Dr. Roth should be prohibited from providing this testimony.

CONCLUSION

Based on the foregoing, Dr. Roth should be precluded from giving opinions on: (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"); (2) the design of Defendants' transvaginal mesh products at issue, including whether or not the design of those devices is reasonable; (3) any opinions regarding the safety and efficacy of TVT or TVT-O, or in the alternative, any opinions regarding differences in safety and efficacy rates between the TVT mechanically cut mesh and the TVT laser cut mesh; and (4) his statements about the safety and efficacy of Defendants' products based on his own practice.

²² Id. at 20:22-21:18. Dr. Roth testifies that he can't comment on whether or not he is relying on the medical literature for his opinion that the safety profile for the mechanically cut mesh and the laser cut mesh is the same.

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Respectfully submitted,

/s/Jeffrey M. Kuntz

Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett

Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Jeffrey M. Kuntz
Attorney for Plaintiffs